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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/625,137 | 07/25/2000 | Pramod K. Srivastava | 8449-123-999 | 8478 |

20583 7590 11/02/2005

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

YAEN, CHRISTOPHER H

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1643

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 09/625,137 | Applicant(s) SRIVASTAVA, PRAMOD K. | |
| | Examiner Christopher H. Yaen | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 80,81,83-92,94-96,104-106 and 109-117 is/are pending in the application.
- 4a) Of the above claim(s) 85-87 and 89-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80,81,83,84,88,94-96,104-106 and 109-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Srivastava

1. The amendment filed 8/18/2005 is acknowledged and entered into the record. Accordingly, claims 1-79, 82, 93, 97-103, and 107-108, are canceled without prejudice or disclaimer, and claims 113-117 are newly added.
2. Claims 80-81, 83-92, 94-96, 104-106, and 109-117 pending, claims 85-87 and 89-92 are withdrawn as being drawn to a non-elected invention.
3. Claims 80-81, 83-84, 88,94-96, 104-106, and 109-117 are examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 80-81,83-84,88,94-96,104-106,109-112, and now newly added claims 113-117 under 35 USC § 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the specification of the instant application is enabling for the instant invention. Specifically, applicant argues that the specification provides "numerous examples of the claimed screening method as well as guidance with respect to how to obtain test compounds" such as small molecules. To support this argument, applicant points to the specification at pages 28-32, wherein the specification provides examples of binding assays that could be used by the skilled artisan to practice the claimed method. Applicant's

arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. The method objective of claimed invention is the identification of a compound that modulates a HSP- α 2M receptor mediated process. Thus, it would be expected that one of skill in the art would be able to identify a compound that is capable of modulating a HSP- α 2M receptor mediated process without undue experimentation by using the claimed method. The instant method specifies the contacting of a small molecule with 1) a ligand binding fragments of α 2M receptor, and 2) a HSP, HSP binding fragment or a HSP-peptide complex; and measuring the levels of HSP binding, HSP uptake, and HSP mediated antigen presentation activity. The specification does not teach any particular test agent or small molecule which would perform the function of modulating a HSP- α 2M receptor mediate process as intended. Instead, what the specification has prophetically provided is guidance on methods of determining HSP activities, such as binding, uptake activity, and antigen "representation". The specification has not provided any nexus between determining the levels HSP activities to means of "modulating a HSP- α 2M receptor mediated process" as claimed. Essentially, what the specification has provided is a method of screening for HSP activities.

The specification does not teach any correlation between the claimed HSP activities and the ability to modulate the HSP- α 2M receptor processes. No guidance in the form of working examples has been set forth to correlate HSP activities with HSP-

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α 2M receptor processes as claimed. As such, one of skill in the art could not reasonably expect success in identifying a test compound or small molecule which would modulate a HSP- α 2M receptor mediated process. Applicant further argues that the findings of the *University of Rochester v. G.D. Searle & Co*, 249 F. Supp. 2d 216 (W.D.N.Y. 2002), and 358 F.3d 916, 69 USPQ.2d 1886 (BNA) (Fed Cir Feb 13, 2004) are not relevant to the instant claims because the claims of that particular case are not analogous to those instantly claimed. Specifically, applicant argues that in *Rochester v. Searle*, the claims were drawn to a method of inhibiting, while those of the instant are drawn to a screening method. However, the Federal Circuit upheld the decision rendered from United States District Court regarding the invalidity of U.S. 6,048,850. The court concluded that although the patent provided an assay for identifying selective PGHS-2 inhibitors, and teachings for how to use such compounds once identified, the patent lacked the "necessary link" between the two stages, because it did not teach how to find a compound which actually worked as a selective inhibitor. The court concluded that the patent gave "previous little guidance" on how to find such a suitable compound. The court states that "at most, its description will enable a person of ordinary skill in the art to attempt to discover [original emphasis] how to practice the claimed invention. That is not enough". The court concluded that the patent did not succeed in taking the last critical step of actually identifying a suitable compound, or at least developing a process through which one of skill in the art would be directly led to such a compound.

The claims at issue in the *Rochester v. Searle* are similar in nature to the instant invention. The instant specification teaches a method to screening for compounds or

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small molecules. The specification provides teachings on how to use the test compound or small molecules once it is identified as modulators of HSP activity. The specification does not provide the necessary link between the two stages because it does not teach how to find a compound which actually works as a modulator for HSP- α 2M receptor processes.

Therefore the rejection of claims under 35 USC 112, 1st paragraph is maintained for the reasons of record and newly argued herein.

All other rejections and objections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed on 8/18/2005.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
October 26, 2005


CHRISTOPHER YAEN
PATENT EXAMINER